DETAILED ACTION

Status of the Application

Receipt of the Response to Non-Final Office Action, Applicant's Arguments/Remarks, the Amendment, the Declaration under 37 C.F.R. 1.132 and the request for extension of time (3 months granted) all filed 07/02/08 is acknowledged.

Claims 1-20, 28 and 30-39 are pending in this action. New claims 36-39 have been added. Claims 21-27 and 29 have been cancelled. Claims 1-20, 28 and 30-39 stand rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-20, 28 and 30-35 under 35 U.S.C. 103(a) over Debendetti et al. (USPN 6,063,910) in view of Merrified et al. (PCT Publication No. WO 00/37169) has been maintained.

The rejections of record can be found in the previous Office Actions (filed 11/01/06 & 01/11/08).

Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Debendetti et al. (USPN 6,063,910) in view of Merrified et al. (PCT Publication No. WO 00/37169).

The rejection of claims 1-20, 28 and 30-35 is maintained and applied to newly added claims 36-39. Debendetti teaches a process for producing microparticles, particularly protein microparticles, from a solution by anti-solvent re-crystallization using a supercritical fluid. The process may be used to make particles of proteins, such as insulin (see col. 2, lines 22-30); Example 2 and Claim 8.

The reference suggests and teaches the presence of an aqueous solvent (col. 6, lines 23-32). The secondary reference of Merrified is relied upon for the teaching of the use of a modifying agent in the antisolvent (as discussed in the Office Action dated 01/11/08).

The instant method would be *prima facie* obvious to one of ordinary skill in the art given the combined teachings of Debendetti and Merrified, as explained and set forth in the previous Office Action of record.

Response to Arguments

Applicant's arguments filed 07/02/08 have been fully considered but they are not persuasive.

- **35 U.S.C. Rejection over Debendetti et al. (USPN 6,063,910) in view of Merrified et al. (WO 00/37169):**

With regards to the rejection of record, Applicant herein argues, "Debendetti fails to teach the aqueous fluid of the present invention and fails to teach a fluid that is substantially void of an organic solvent. Rather, Debendetti teach that the fluid must comprises at least one non-aqueous solvent."

Applicant's arguments have been fully considered but they are not persuasive. Debendetti, contrary to Applicant's arguments, does teach that aqueous solvents can be used, albeit, the reference states that this would yield a lower production of small particle protein (col. 6, lines 23-32). This teaching indicates that the use of aqueous solvents is permissible, although could be interpreted as a non-preferred embodiment in the teachings of Debendetti. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

"A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Applicant argues that "Debendetti fails to teach a fluid that is substantially void of an organic solvent". This was not persuasive since at least the generic claims do not require that the process be "substantially void of an organic solvent". Thus, Applicant's arguments are not commensurate in scope with the claims which permit use of organic solvents. Moreover, with respect to claim 39, it is noted that the claim recites "substantially free of organic solvent". However, the "substantially free (of organic solvent)" does not *completely* exclude the presence of the organic solvent. Furthermore, it is noted that claims utilize "including" or "comprising" language which would not exclude the presence of organic solvents. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended.").< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). Hence, Applicant's arguments were not rendered persuasive. The instant claims, as presently recited remain broad enough to read on the combined teachings of the Debendetti and Merrified references.

Applicant argues unexpected and surprising results achieved by the instant invention as shown in the specification at page 10, lines 1-2. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., use of aqueous fluids enabling concentrated solutions to be processed with minimal risk of deactivation of biological activity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The Examiner cannot read limitations that are not in the claims as distinguishing over the prior art references.

The Declaration under 37 C.F.R. 1.132 filed 07/02/08 has been considered but was not persuasive. Examiner acknowledges Applicant's arguments that are responsive to the previous Examiner's statement indicating that non-linear behavior may be predictable if a proper model is found. Such arguments have been noted. Applicant states the impossibility of predicting as to whether a linear or non-linear model should be applied for a particular supercritical system, given the Ting et al., Hutchinson et al. and Juoyban et al. references. While this may be the case, these findings do not aid in distinguishing the instant invention over the explicit teachings of the art. The primary reference of Debendetti teaches that aqueous solvents can be used. The secondary reference of Merrified fills the deficiency of the primary reference, namely, in their teaching of the use of a modifying agent with the antisolvent. Applicant's arguments referencing and comparing Example 2 of the present application with that of Example 2 of Debendetti was not persuasive. The higher concentration and thus higher yield argued by Applicant based on the

example of the present application versus that of the prior art was not persuasive since the instant claims are generic in scope and are not representative of the specific examples (i.e., Example 2) of the instant specification, which present specific ingredients with defined amounts and concentrations under specific conditions. The examples do not parallel nor establish the scope of claims presented by Applicant and thus were not held to be persuasive.

The rejections of record have been maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns